



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

94896d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

June 28, 2004

WARNING LETTER

NWE-28-04W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mark S. Collins, Manager and Co-owner
Jack Collins, Co-owner
Collins Brothers Chowder Co.
59 Temple Street
Nashua, New Hampshire 03060

Dear Mr. Collins :

On March 23 and 24, 2004, we inspected your seafood processing facility, located in Nashua, New Hampshire. We found that you have serious deviations from the seafood Hazard Analysis Critical Control Points (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly your clam chowder in a heat sealed plastic bag has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find this Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However, your firm does not have a HACCP plan for refrigerated clam chowder packaged in a heat sealed plastic bag to control the food safety hazards of pathogen growth and toxin formation including that of *Clostridium botulinum*.
- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for the eight (8) areas of sanitation required for the processing of clam chowder including safety of water that comes in contact with food or food contact surfaces, condition and cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing facilities, protection of food, food packaging material and food contact surfaces from adulteration with toxicants, proper labeling, storage and use of toxic substances, control of employee health conditions and exclusion of pests from the food plant.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as a completed HACCP plan, or other useful information that would assist in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Collins Brothers Chowder Co.
Nashua, NH 03060
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Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail L. Costello", written over the printed name.

Gail L. Costello
District Director
New England District